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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,091	08/06/2003	Anne M. Pianca	AB-185U	6980
23845 7590 08/02/2007 ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			EXAMINER KAHELIN, MICHAEL WILLIAM	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 08/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/635,091		PIANCA ET AL.	
	Examiner		Art Unit	
	Michael Kahelin		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "not movable with respect to each other at all times" is lacking support in the originally filed application. Applicant argued in the remarks of 5/16/2007 that support for this limitation is provided through the disclosure that the tube "can be drawn over the core by pulling the tube through a die", and that the assembly is quickly quenched, which sets the nitinol outer tube over the core. Applicant further argued that "to set" means to make the core at all times immovable relative to the outer covering. However, the use of a die and quickly quenching speaks nothing to the movability of the core and outer covering because the relationship between the core and outer covering, when coming through the die, could be such that no interference fit exists between the two elements, and there is no disclosure that explicitly or implicitly indicates that such an interference fit exists. Further, the heating and quenching step does not inherently indicate that the two

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elements possess an interference fit because the heating and quenching could be performed to relax the internal stresses of the metal, not fix them to each other. The Examiner is of the position that "to set" does not necessarily mean to make immovable at all times because in common use, "to set" does not imply movability (e.g., "to set a box on a table" does not mean that said box cannot be moved at a later time). Further, the limitation of "at all times" is lacking support, and contradicted, by the disclosure of the manufacturing processes on pages 13 and 14 of the specification. The disclosure of pulling the tube over the core indicates that the core and tube are movable with respect to each other at the time of manufacturing (not meeting the "at all times" limitation). Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10, 13-18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Gates et al. (US 5,522,875, hereinafter "Gates").

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4. In regards to claims 1-3, 14, and 18, Gates discloses a lead/stylet combination (Fig. 1) wherein the stylet comprises an outer covering (201) and inner core (130) that are immovable with respect to each other (Figs. 15 and 16). Further, the inner and outer elements inherently possess different elastic and buckling properties because the inner core is made of 304 stainless steel (col. 7, line 54) and the outer covering is made of Nitinol (col. 9, line 45).

5. In regards to claim 4, the outer covering defines a tube (Fig. 16) and the core is pre-formed because it is formed before implantation.

6. In regards to claim 5, the stylet is isodiametric over a portion of the length (Fig. 15).

7. In regards to claims 6, 7, 9, and 10, the outer covering has a variable wall thickness with respect to a single coil (i.e. the covering is thicker between windings of the coil than at the peaks of the coils) and is substantially constant over the gross stylet length.

8. In regards to claim 8, the stylet has variable outer diameter over a portion of its length, for instance the handle (Fig. 15).

9. In regards to claim 13, the core is pre-stressed because it is bent into a coil, thusly placing the inner surface of the coil in a compression state.

10. In regards to claims 16 and 20, the system is capable of DBS application because it is of a size capable of traversing blood vessels and will fit within the cranium.

11. In regards to claim 17, the outer covering defines an annulus because it "wraps around and covers" the core (col. 9, lines 34).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 11, 12, 15, and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Gates. Gates discloses the essential features of the claimed invention except for providing a composite stylet utilizing the claimed materials. It is well known in the implantable device arts to provide stylets and guidewires of the claimed material combinations to achieve desired torque, buckling, and bending characteristics for a specific implantation application. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Gates' stylet with

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the claimed material combinations to achieve desired torque, buckling, and bending characteristics for a specific implantation application.

Response to Arguments

15. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reynolds et al. (US 7,074,197) and Poor et al. (US 6,607,496) are further examples of composite support structures.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

MWK
7/27/07

GE
GEORGE R. EVANISKO
PRIMARY EXAMINER

7/30/07